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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,757	07/03/2000	TONI M. KUTCHAN	J&J-1673	4581

7590 05/27/2005
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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/486,757	Applicant(s) KUTCHAN ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communications filed 12-10-04.

Claims 57-62 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-10-04 has been entered.

Response to Arguments and Amendments

Withdrawn Rejections

The declarations under 37 CFR 1.132 filed 12-10-04 are sufficient to overcome the rejection of claims 57-62 based upon lack of enablement.

Any rejections not repeated in this Office action are hereby withdrawn.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to products obtained and methods of producing poppy plant alkaloids comprising the transformation or transfection of alkaloid poppy plants with a polynucleotide comprising SEQ ID NO: 10 or any variant or fragment thereof. The specification and claims do not adequately describe the genus comprising alkaloids isolated utilizing the claimed methods, nor do they adequately describe the genus comprising any variant or fragment of SEQ ID NO: 10 that leads to production of the claimed alkaloid products. The instant disclosure describes the transformation and field testing of various poppy lines modified to contain the cytochrome P-450 reductase transgene of SEQ ID NO: 10, whereby thebaine, morphine, codeine and "total alkaloid" content was compared to parent strains. The composition of the genus comprising total alkaloid was not disclosed, however. The disclosure does not adequately describe the concise structural features of the genera comprising total alkaloids, or comprising variants or fragments of SEQ ID NO: 10 that would confer cytochrome p450 reductase activity, whereby higher or different alkaloid content of transformed plants is achieved. One of skill in the art would reasonably conclude that the instant disclosure does not adequately describe a representative number of species of the genera comprising

isolated alkaloids, or comprising fragments or variants of SEQ ID NO: 10 that confer changes in poppy plant alkaloid production.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57- 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosco et al in view of Fist et al.

The claims are drawn to methods of producing altered poppy plant alkaloids (and alkaloids produced by these methods) comprising transforming or transducing plants with a polynucleotide comprising SEQ ID NO: 10 encoding cytochrome P-450 reductase

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and extracting the alkaloid(s) morphine, codeine, thebaine and oripavine, from the straw of transformed poppy plants.

Rosco et al (Arch. Biochem. Biophys. 348(2): 369-377, 1997) teach the cloning and heterologous expression of cytochrome P-450 reductase (CPR) encoded by SEQ ID NO: 10. Rosco et al also teach the role of CPR in alkaloid (morphine) biosynthesis in poppy plants (see the abstract and bridging paragraph, pp. 369-370; figures 1 and 2, p. 370; and accompanying sequence alignment data between Accession No. U67185 of Rosco et al and SEQ ID NO: 10 of the instant application).

Rosco et al do not teach the extraction of the alkaloids morphine, codeine, thebaine and oripavine from the straw or opium of poppy plants for enhanced alkaloid yields.

Fist et al (USPN 6,376,221, priority date of July 11, 1996) teach the extraction and increased yields of various alkaloids, including morphine, codeine, thebaine and oripavine, from the straw of poppy plants to enhance the availability of these commercially valuable alkaloid products (see the abstract; col. 3-4; col. 6-8; col. 11-14; col. 16, claims 1-10).

It would have been obvious to one of ordinary skill in the art to transduce poppy plant hosts with an isolated polynucleotide of SEQ ID NO: 10 for producing altered amounts of alkaloids, including morphine, because Rosco et al teach the cloning, characterization and heterologous expression of this recombinant CPR, as well as teaching the role of CPR in alkaloid production in poppy plants. One of ordinary skill in the art would have been motivated to transduce appropriate poppy plant hosts with SEQ

ID NO: 10 in order to enhance production of various alkaloids, including morphine, because the commercial importance of such products are well known in the art, the CPR had been made available in recombinant form by Rosco et al, and the technology to extract commercially valuable products such as morphine were well known in the art, as reviewed by Rosco et al (figures 1 and 2, p. 370). One of ordinary skill in the art would have extracted enhanced yields of various commercially available alkaloids, including morphine, codeine, thebaine and oripavine, from the straw of poppy plants and utilizing the methods previously disclosed by Fist et al because these methods were known to enhance the yields of these costly alkaloids. One of ordinary skill in the art would have expected that increasing the expression of CPR in an appropriate poppy plant host, and extracting the alkaloids using the methods set forth by Fist et al, would lead to increased production of commercially valuable alkaloid products, including morphine, codeine, thebaine and oripavine, from the straw of poppy plants, because this had been taught previously by Rosco et al (see bridging paragraph, pp. 369-370) and by Fist. Therefore, the instant invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the

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Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JZ
5-25-05

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